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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,388	11/27/2001	Alan P. Carpenter, JR.	PH-7201	1791

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	8

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,388	CARPENTER,, ALAN P.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/17/02; 12/13/02; and 5/12/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,38,39,47-63,65 and 66* is/are rejected.

7)☒ Claim(s) *8,10-37,40-46 and 64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2&4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence compliance notice* .

APPLICANT'S INVENTION

1. Applicant's invention is directed to a method of concurrent imaging as set forth in independent claim 1.

Note: Claims 1-66 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group XVI in Paper No. 7, filed 5/12/03, is acknowledged. The traversal is on the ground(s) that the Examiner has not shown that there is a serious burden on the Examiner to examiner the full scope of the claims and that the Examiner has not shown that the inventions are distinct or independent. This is found non-persuasive because contrary to Applicant's assertion that any search of the prior art in regards to the various Groups will reveal whether any prior art exists as to the other groups, a search is directed to references which would anticipate or render the invention obvious and therefore requires a search of relevant literature in many different subject areas. Thus, since the groups of targeting agents do not share a common structure, a prior art reference which anticipates or renders obvious one targeting agent would neither anticipate nor render obvious another agent. Hence, separate searches are necessary for the groups of targeting agents. Also, it should be noted that while the groups classify in the same area, each represents a patentably distinct group of agents with distinct physical and functional characteristics. Furthermore, while the Examiner does not find Applicant's arguments persuasive for the reasons above, the Examiner has modified the restriction as suggested in Applicant's response filed 5/12/03, Paper

No. 7, page 45. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

Modified Restriction

Modified Group I Claims 1-66, drawn to a method of imaging comprising administering a vitronectin receptor targeted imaging agent wherein the targeting agent has the sequences, cyclo (Arg-Gly-Asp-Tyr-...Val) (see claim 20, first compound on page 245); cyclo (Arg-Gly-Asp-Phe-Lys) (see claim 20, second compound on page 246); cyclo(Arg-Gly-Asp-Tyr-Lys) (see claim 20, third compound on page 246); Phe-Glu(cyclo(Lys-Arg-Gly-Asp-Phe)-cyclo (Lys-Arg-Gly-Asp-Nal) (see claim 20, fourth compound on page 246); cyclo (Arg-Gly-Asp-Nal-Lys) (see claim 20, fifth compound on page 246); Glu (cyclo(Lys-Arg-Gly-Asp-Nal)-cyclo(Lys-Arg-Gly-Asp-Nal) (see claim 20, sixth compound on page 246); Glu (O-cyclo (Lys-Arg-Gly-Asp-Phe)-O-cyclo (Lys-Arg-Gly-Asp-Phe) (see claim 20, eighth compound on page 246); Glu(O-cyclo(Tyr-aminopropyl)-Val-Arg-Gly-Asp)-O-cyclo(Tyr(3-aminopropyl)-Val-Arg-Gly-Asp) (see claim 20, compound bridging pages 246-247); cyclo(Arg-Gly-Asp-Lys(N-5-carbonyl-2-pyridinyl-diazenido)-Val (see claim 20, first complete compound listed on page 247, lines 4-5); cyclo(N-Me-Arg-Gly-Asp-ATA-Lys(N-5-carbonyl-2-pyridinyl-diazenido) (see claim 20, compound listed in lines 17-18 on page 247); Glu(cyclo-Lys-Arg-Gly-Asp-Phe)-cyclo(Lys-Arg-Gly-Asp-Phe) (see claim 22, first compound on page 248); and Glu-cyclo(Arg-Gly-Asp-Phe-Lys)2-dodecane1,12-dione (see claim 42, last compound on page 262).

Modified Group II Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor targeted imaging agent wherein the targeting agent has the sequences, cyclo(Lys-5-carbonyl-2-pyridinyl-diazendio-Phe-Asp-Gly-Arg (see claim 20, compound on lines 7-8 on page 247); 5-carbonyl-2-pyridinyl-diazenido-Glu-cyclo(Lys-Phe-Asp-Gly-Arg)-cyclo(Lys-Phe-Asp-Gly-Arg) (see claim 20, compound listed in lines 10-12 on page 247); and cyclo(Phe-Lys-5-carbonyl-2-pyridinyl-diazenido-Asp-Gly-Arg (see claim 20, compound listed in lines 14-15 on page 247).

Modified Group III Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor targeted imaging agent wherein the targeted imaging agent has the sequence, cyclo(Arg-Val-Tyr-Asp-...Gly) (see claim 20, second compound on page 245).

Modified Group IV Claims 1-21, 23-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor targeted imaging agent wherein the targeted imaging agent has the sequence, cyclo(Cit-Gly-Asp-Phe-Lys-5-carbonyl-2-pyridinyl-diazenido) (see claim 20, compound listed in lines 20-21 on page 247).

Notes: (a) The modified restriction is as suggested by Applicant in the response filed 5/12/03, Paper No. 7, page 45. (b) Claims appearing in more than one group will only be examined to the extent that they read on the elected group. (c) Modified Group I was examined because it contained Applicant's elected species. The search was not extended beyond modified group I. Thus, ***Applicant is respectfully requested to cancel all subject matter not directed to the elected invention.***

112 SECOND PARAGRAPH REJECTION

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39, line 3: The claim as written is ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written reads on 'a temperature activated gaseous precursor'; however, one of ordinary skill in the art would not be able to ascertain what precursor(s) is/are encompassed in the claim. Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

Claim 56, lines 3-4: The claim as written is ambiguous because of the phrase 'synergistically effective amount'. Applicant is respectfully requested to clarify what is intended by the phrase in order that one may readily ascertain what is being claimed. The rejection may be overcome by Applicant incorporating in a range that identifies a synergistically effective amount; however, whatever the range or specified amount must be supported in the specification.

STATUTORY DOUBLE PATENTING

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-7, 9, 38, 39, 47-63, 65, and 66 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 29, 30, and 39-59 of copending Application No. 10/213,713. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

CLAIM OBJECTIONS

7. Claims 8, 10-37, 40-46, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

PRIORITY DOCUMENT

8. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the Philippines on 11/27/00. It is noted, however, that applicant has

not filed a certified copy of the PHILIPPINES 7201P1 application as required by 35 U.S.C. 119(b).

COMMENTS/NOTES

9. It should be noted that no prior art has been applied against Applicant's claims; however, Applicant ***must*** address and overcome the double patenting and 112 rejections above.

The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of concurrent imaging in a mammal as set forth in independent claim 1 wherein the specific vitronectin target peptide sequences comprises Arg-Gly-Asp as set forth in modified Group I of the restriction above and claims 20, 22, 28, and 42.

Note: It should be noted that the search has not been extended beyond modified Group I.

10. The instant application contains sequences (e.g., page 84, line 3; page 84, line 15, etc.); however, Applicant has not complied with the sequence rules. Please see the attached notice regarding compliance with the sequence rules.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640.

The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

September 3, 2003

NOTICE TO COMPLY WITH THE SEQUENCE RULES

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN THREE MONTHS (see MPEP 2421.03) FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached notice regarding compliance with the sequence rules.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at (703) 308-4556. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30; November 15, 1989.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Monday - Friday, 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1619

September 3, 2003

Application No. 09/995,388

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached marked-up copy of the "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other: _____

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

Please return a copy of this notice with your response.